DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

December 2, 2014

Stryker Endoscopy
Mr. Golnaz Moeini
Senior Regulatory Affairs Analyst
5900 Optical Court
San Jose, California 95138

Re: K142310
Trade/Device Name: Stryker® IRF Light Source and Safelight Cable
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: OWN
Dated: November 4, 2014
Received: November 5, 2014

Dear Mr. Moeini:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142310

Device Name
Stryker® IRF Light Source and SafeLight Cable

Indications for Use *(Describe)*
The Stryker® IRF Light Source and SafeLight Cable are indicated for use to provide real-time endoscopic visible and near-infrared fluorescence imaging. The Stryker® IRF Light Source and SafeLight Cable enable surgeons to perform minimally invasive surgery using standard endoscope visible light as well as visual assessment of vessels, blood flow and related tissue perfusion, and at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct and common hepatic duct), using near infrared imaging.

Fluorescence imaging of biliary ducts with the Stryker® IRF Light Source and SafeLight Cable is intended for use with standard of care white light and, when indicated, intraoperative cholangiography. The devices are not intended for standalone use for biliary duct visualization.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Section 5. 510(k) Summary

1. General Information

510(k) Sponsor	Stryker Endoscopy
Address	5900 Optical Court San Jose, CA 95138
FDA Registration Number	2936485
Correspondence Person	Golnaz Moeini Sr. Regulatory Affairs Analyst Stryker Endoscopy
Contact Information	Email: golnaz.moeini@stryker.com Phone: 408-754-2755
Date Prepared	November 04, 2014

2. Proposed Device

Proposed Device:

Proprietary Name	*Stryker® Infrared Fluorescence (IRF) Imaging System [consists of: IRF Light Source and SafeLight Cable, 1488 Camera Control Unit, IRF Coupler, IRF Laparoscope, and Fluorescence ICG Kit]*
Common Name	*Light Source, Illuminator*
Classification Name	Confocal Optical Imaging
Regulation Number	21 CFR 876.1500
Product Code	OWN
Regulatory Class	II

3. Predicate Device

Predicate Device

Proprietary Name	*Intuitive Surgical® da Vinci® Imaging Vision System (K124031)* *Video Camera with Infrared Compatibility (K132785)* *Stryker® Laparoscope (K910132)*
Premarket Notification	K124031 K132785 K910132
Classification Name	Confocal Optical Imaging
Regulation Number	21 CFR 876.1500
Product Code	OWN
Regulatory Class	II

4. Device Description

The *Stryker® Infrared Fluorescence (IRF) Imaging System* is an endoscopic illumination and imaging system for real-time high definition (HD) visible light and near-infrared dye fluorescence imaging of indocyanine green (ICG) used during minimally invasive surgery. The *Stryker® Infrared Fluorescence (IRF) Imaging System* consists of the following main components:

- A light source console and a light cable for outputting light within a visible light spectrum as well as near-infrared light spectrum.
- A camera control unit for processing near-infrared and visible light images.
- A coupler that is attached to the laparoscope and a camera head. It is optimized for near-infrared fluorescence imaging in addition to visible light imaging.
- A laparoscope for visible light and near-infrared light illumination and imaging.
- A *Fluorescence ICG Kit* containing *IC-Green®* drugs and Aqueous Solvents

The Stryker system uses an illuminator with a laser light source to illuminate the area of surgery. The ICG is administered intravenously prior to image obtainment. A laser light is illuminated to the site of the surgery using a laparoscope. Upon the absorption of laser light, the ICG passing through the vessels are excited causing an infrared light to be emitted. The camera system captures the infrared emission, processes the image and displays it on a surgical display.

5. Indications for Use

The *Stryker® IRF Light Source* and *SafeLight Cable* are indicated for use to provide real-time endoscopic visible and near-infrared fluorescence imaging. The *Stryker® IRF Light Source* and *SafeLight Cable* enable surgeons to perform minimally invasive surgery using standard endoscope visible light as well as visual assessment of vessels, blood flow and related tissue perfusion, and at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct and common hepatic duct), using near infrared imaging.

Fluorescence imaging of biliary ducts with the *Stryker® IRF Light Source* and *SafeLight Cable* are intended for use with standard of care white light and, when indicated, intraoperative cholangiography. The devices are not intended for standalone use for biliary duct visualization.

6. Comparison of Technological Characteristics with the Predicate Device

As noted above, the *Stryker® Infrared Fluorescence (IRF) Imaging System* is equivalent to the following cleared devices in terms of its indications for use, design technology and performance specification:

With respect to the light source console and light cable, the proposed Stryker illuminator console is substantially equivalent to *Intuitive Surgical® da Vinci® Imaging Vision System (K124031)* in laser light output and indication for use.

With respect to the use of a contrast drug agent (indocyanine green (ICG)), the proposed *Stryker Infrared Fluorescence (IRF) Imaging System* device is similar to the predicate *Intuitive Surgical® da Vinci® Imaging Vision System* (K124031) device in that the proposed device is also intended to be used with an FDA approved contrast agent drug, indocyanine green (ICG), to achieve the proposed indications for use.

With respect to the camera system, the proposed Stryker camera is substantially equivalent to *Stryker® 1488 HD Video Camera with Infrared Compatibility (K132785)* since they both consist of a camera control unit and a coupler component and are essentially the same in design and indication for use with minor modification to optimize near-infrared light image processing and transmission.

With respect to the laparoscopes, the proposed Stryker laparoscope is substantially equivalent to *Stryker® Laparoscope (K910132)* since they are both the same in design and indication for use with very minor modification to the proposed device to enhance near-infrared images.

The Stryker illuminator device is essentially using a similar laser illumination technology as the already cleared *Intuitive Surgical® da Vinci® Imaging Vision System* and has the same clinical use. The camera control unit, coupler and laparoscopes are optimized to enable the visualization of fluorescence imaging. The ICG drug has had a long history of use with an established safety track record. The information included in this submission will establish the substantial equivalency of the proposed devices to the specified predicates.

7. Performance Data

Safety and performance of the *Stryker® Infrared Fluorescence (IRF) Imaging System* has been evaluated and verified in accordance with design specifications and applicable performance standards through biocompatibility assessment, electrical safety and EMC testing, software validation, bench testing and animal testing. Additionally, an investigator initiated clinical study was conducted with IRB oversight and approval as a non-significant risk study at The Ohio State University utilizing the proposed device (*Stryker® Infrared Fluorescence (IRF) Imaging System)*. The result of this clinical study is published in *Surgical Endoscopy Journal.* Additional clinical evaluation supporting the safety and effectiveness of near-infrared fluorescence imaging system has been gathered and summarized in the clinical section (see *section 20, Performance Testing-Clinical*, for the summary of the relevant clinical literatures). The following performance testing are conducted and summarized in this submission:

- Biocompatibility was assessed in accordance to *ISO 10993-1:2009 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process and related collateral standards for patient contacting materials*.

- The *SafeLight Cable, IRF Coupler* and *IRF Laparoscopes* are designed to be sterilized using any of the following sterilization methods: *STERRAD® (100S /NX™/100NX™), Steris Amsco® V-PRO™*, and *Ethylene Oxide (EO).* The Sterilization validation for each sterilization method was assessed in accordance with *ISO 14937:2009- Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices.* For all sterile devices, the Sterility Assurance Level (SAL) is 10^{-6}.

- Electrical Safety and electromagnetic compatibility testing was performed in accordance to *IEC 60601-1:2005- Medical electrical equipment- Part 1: General requirements for basic safety and essential performance* and *IEC 60601-1-2:2007- Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance- Collateral Standard: Electromagnetic disturbances – Requirement and tests,* respectively. Testing indicates that the proposed device conforms to the aforementioned voluntary standards.

- The software validation activities were performed in accordance with *IEC 62304:2006/AC: 2008- Medical device software – Software life cycle processes* as well as the FDA Guidance documents, *"Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"*.

- Bench performance testing was conducted to ensure that the device functioned as intended and met design specifications and acceptance criteria. Test results obtained verified the safety and effectiveness of the devices per design specifications and applicable standards.

- Animal testing conducted under Good Laboratory Practice (GLP) validated the in-vivo fluorescence imaging capability of the *Stryker® Infrared Fluorescence (IRF) Imaging System.*

- A full clinical literature evaluation was performed to assess the safety and efficacy of *Stryker® Infrared Fluorescence (IRF) Imaging System* for near-infrared fluorescence cholangiography during laparoscopic cholecystectomy and for near-infrared fluorescence perfusion angiography.

8. Conclusion

Based on the information submitted in this premarket notification, and based on the indications for use, technological characteristics, performance testing and technological comparison to the predicate devices, the *Stryker® Infrared Fluorescence (IRF) Imaging System*

raises no new questions of safety and effectiveness and is substantially equivalent to the predicate devices in terms of safety, efficacy and performance.